



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

May 25, 2001

MEMORANDUM

EPA Reg. No.: 279-3163  
Product Name: TALSTAR® 0.2G LAWN GRANULAR INSECTICIDE  
DP Barcode: D274019  
Case No: 039832  
Submission: S590447  
Chemical: 128825 Bifenthrin

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505C)

*Byron T. Backus*  
*5/25/2001*

To: Tracy Keigwin/Arnold Layne, PM 03  
Insecticide Branch  
Registration Division (7505C)

Registrant: FMC Corporation Agricultural Products Group

**ACTION REQUESTED:** "Here is another tox issue related to our recent CRP letter to FMC. EPA Reg. No. 279-3163 triggers CRP because the oral LD50 is less than 1500 mg/kg... [Now] they are claiming similarity to EPA Reg. No. 279-3130 in order to get out of...CRP requirements..."

COMMENTS AND RECOMMENDATIONS:

1. According to TRB's electronic records files, an acute oral study (in MRID 43780502) for EPA Reg. No. 279-3163 was reviewed by S. Oonithan, with a cover memorandum dated March 5, 1996. In this review it is stated that the test material was administered as a homogeneous suspension at 10% w/v in Tween [80] at a dosage

rate of 1000 mg of test material/kg. There was also a vehicle control group. In the results section of the review it is stated that: "There was no mortality in the test. The toxicologic symptoms in the treated and vehicle control groups included abdominal gripping, abdominogenital staining, and diarrhea. All animals gained weight by day 14.

2. Although the study in MRID 43780502 was classified as acceptable, this reviewer is somewhat concerned about the vehicle that was used [Tween 80, according to a copy of an E-mail from a representative of the registrant], as its physiological effects (which included diarrhea) may have significantly reduced the absorption of the active ingredient. However, in any case the results of this particular study indicated only that the oral LD50 value of this formulation was above 1000 mg/kg, and could not be used as supporting data to argue against imposition of Child-Resistant Packaging (CRP), required of products with oral LD50 values  $\leq 1500$  mg/kg.
3. The registrant has now cited another acute oral LD50 study (in MRID 42094202) conducted on a 0.2% bifenthrin-containing "granular" formulation. The formulation is currently registered under EPA Reg. No. 279-3130; this study was reviewed and classified as acceptable by L. Markarian (3/18/1992). According to the review there were no mortalities among 5M and 5F rats receiving a dose of 5000 mg/kg of this formulation, administered as a 25% w/v mixture (suspension?) in margarine.
4. In addition, TRB notes that the signal word for technical (89% active) bifenthrin (EPA Reg. No. 279-3055) is WARNING. The signal word implies that the oral LD50 for the technical can be no worse than 50 mg/kg; an end-use product containing 0.2% bifenthrin would then have an estimated oral LD50 (from the presence of bifenthrin) of, on a worst-case-basis:

$$50 \text{ mg/kg} \times 0.89/0.002 = 22,250 \text{ mg/kg}$$

5. The inert ingredients in both formulations (EPA Reg. Nos. 279-3130 and 279-3163) are of minimal concern with respect to their ingestion hazard potential.
6. Taking the factors above into consideration, it is concluded that the registrant can cite the acute oral LD50 study (in MRID 42094202) conducted for EPA Reg. No. 279-3130 as applicable (supporting data) for EPA Reg. No. 279-3163, which can then be considered to have an oral LD50 value  $\geq 5000$  mg/kg. EPA Reg. No. 279-3163 would then not require CRP on the basis of its oral LD50 value.
7. For the purposes of this action, TRB has not examined the referenced study in MRID 42094202, nor has TRB examined the labels of the two products involved with respect to the acceptability and/or adequacy of their precautionary labeling.